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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,973	09/05/2003	Meir Rosenberg	022719-0047	8809
21125	7590	03/16/2006	EXAMINER	
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/656,973		ROSENBERG, MEIR	
	<b>Examiner</b>		<b>Art Unit</b>	
	Leslie R. Deak		3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 13-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 13-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-8 and 13-16 rejected under 35 U.S.C. 102(e) as being anticipated by US2003/0004495 A1 to Saul.

Saul discloses the invention as claimed in the specification and figures.

Specifically, Saul discloses a method and device for volumetric removal of CSF from a hydrocephalus patient with an implantable, controllable shunt system. Saul discloses a ventricular catheter 12 and peritoneal catheter 14 that are connected via a flow control valve 30. The catheters operate to shunt CSF from the brain ventricle to the peritoneal cavity (see paragraph 0043). The system is operated via controller 32 that operates the movement of the valve 30 with power from source 34.

When CSF fluid drainage is being controlled by volume, sensing device 36 sends signals to the controller 30, which adjusts the valve between an open and closed position based on the signals sent to the controller from the sensor (see paragraphs 0044 and 0045). The sensor reports the volume of flow through the valve, and once the desired volume has been reached (which the controller must determine by comparing

Art Unit: 3761

the measured value to a desired value), the controller sends an electrical control signal to the valve, adjusting the resistance of the valve to open (decreased resistance) or closed (increased resistance) in order to continue or halt fluid flow (see paragraphs 0045, 0046).

With regard to claims 5, 8, and 16, the procedure disclosed by Saul may be repeated, if desired, a set number of times per day, with the time between treatments set to allow the CSF to drain from a reservoir, allowing the patient to adjust to the current resistance of the valve, until a total desired volume of CSF is removed from the ventricular space (see paragraph 27).

With regard to claims 13-15, Saul specifically discloses that his apparatus and method are particularly intended for patients who experience hydrocephalus with "normal" intracranial pressures, i.e, normal pressure hydrocephalus (see paragraph 15).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 9 and 17-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0004495 A1 to Saul as applied above, in view of US 2003/0032915 A1 to Saul.

Saul 495 discloses the apparatus substantially as claimed by applicant with the exception of a pressure sensor. Saul 915 discloses an apparatus and method for controlling CSF drainage through a shunt that uses a pressure differential to determine when there is an increased volume of CSF in the ventricles. Using a change in pressure, rather than a single pressure measurement, enables one to monitor the volume of CSF in the ventricles even when the patient's standalone intracranial pressure remains within a normal range. By subtracting a current pressure value from a baseline pressure value, Saul determines a change in pressure that is indicative of increased volume of CSF in the measured space (see paragraph 0031).

The device includes a ventricular catheter 12, peritoneal catheter 14, and a flow control element 16/30 disposed between the two catheters (see FIG 3). The flow control element 30 is controlled by controller 32, which is programmed to operate the valve in response to changes in the measured pressure differential (see paragraph 0033). Pressure sensor 40 is located on the ventricular catheter 12, with an electrical output 42 that is fed to controller 44. With regard to claims 21-23, the controller drives flow control element 48 based on a variety of programmed algorithms that control drainage of CSF.

With regard to claims 24-26, Saul fails to disclose a second sensor in the system. However, it would have been obvious to one having ordinary skill in the art at the time of invention to add a second sensor and sensing operation to the device and method disclosed by applicant since it has been held that duplication of the working parts of a device or steps of a method involves only routine skill in the art. See MPEP 2144.04.

With regard to claim 26, Saul fails to disclose that the valve is configured for implantation in the peritoneal cavity of the patient. Absent any showing of new or unexpected results of such a change in the location of the valve, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place the valve in the peritoneal cavity, since it has been held that rearranging parts of an invention involves only routine skill in the art. See MPEP 2144.04.

With regard to claim 27, Saul 915 discloses the device as claimed with the exception of a timed shut-off mechanism. Saul 495 discloses that his device may be controlled by a timer or programmable controller in order to control the valve based on a predetermined time schedule in order to prevent overdrainage of CSF from the patient during a single time period (see paragraph 0027). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add an automatic shutoff to the CSF shunt system in order to prevent overdrainage of CSF from a patient during a particular time period.

### ***Response to Arguments***

5. Applicant's amendment filed 19 January 2006 has been entered and considered. Accordingly, the 35 USC 112 rejection of claims 9 and 17-27 is withdrawn.
6. Applicant's arguments filed 19 January 2006 with regard to claim 1 have been fully considered but they are not persuasive.

Applicant argues that Saul 495 fails to disclose a sensor that measures a physiological characteristic of the ventricular cavity. However, applicant's argument is

narrower than the invention actually claimed. Applicant claims a sensor element “for measuring a physiological characteristic...” which is a limitation directed to the intended use of the sensor. Furthermore, a sensor that detects flow from the ventricular cavity senses that there is fluid within the cavity, therefore sensing a physiological characteristic of the ventricular cavity. Therefore, applicant’s claim 1 reads on the Saul 495 device and method.

7. Applicant’s arguments filed 19 January 2006 with regard to claim 17 have been fully considered but they are not persuasive.

Applicant argues that Saul 915 fails to disclose or suggest an external system controller, relying instead on an internal system controller. However, it has been held that rearrangement and separation of the parts of a device disclosed in the prior art is within the skill of a worker in the art. It has been held that constructing a formerly integral structure in various elements and rearranging parts of an invention requires only routine skill in the art. See MPEP § 2144.04.

### ***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

Art Unit: 3761

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**PATRICIA BLANCO**  
**PRIMARY EXAMINER**

*Patricia Blanco*  
3/13/06

*Leslie R. Deak*  
Leslie R. Deak  
Patent Examiner  
Art Unit 3761  
6 March 2006